

## ENZYMATIC THERAPY

INTEGRATIVE THERAPEUTICS INC."

NF Formulas PhytoPharmica
Tyler Encapsulations - Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0465 6

## ENZYMATIC THERAPY & PHYTOPHARMICA\*

825 Challenger Drive, Green Bay, WI 54311-8328 B: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 921.859.9099 2 F. 1920.469.4418 (Phyto)

What Better feels like."

May 23, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Doctor's Choice for 50-Plus Men™	Targeted nutrients for healthy aging*	Vitamin A (75% as beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acid succinate), Vitamin K (as phtonadione), Thiamin (as thiamin HCI) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide and niacin), Vitamin B6 (as pyridoxine HCI), Folic Acid, Vitamin B12 (as cyanocobalamin), Biotin, Pantothenic Acid (as calcium D-pantothenate), Calcium (as calcium carbonate and calcium citrate), Iodine (as potassium iodide), Magnesium (as magnesium aspartate and magnesium oxide), Zinc (as zinc gluconate), Selenium (as L- selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Potassium (as potassium aspartate), Choline Bitartrate, Saw Palmetto (Serenoa repens) berry extract, Sour Cherry (Prunus cerasus) Fruit Extract, Black Tea (Camellia sinensis) Leaf Extract, , Ginger (Zingiber officinale) Rhizome Extract , Green Tea (Camellia sinesis) Leaf Extract, Inositol, Beatine HCI, Grape (Vitis vinifera) Seed Extract, Panax Ginseng Root Extract, Bromelain, Papain, Bilberry (Vaccinium myrtillus) Fruit Extract, Pepsin (acid-stable protease), Lipase, Boron (as sodium borate), Lycopene, Lutein (from Calendula officinalis), Vanadium (as vanadyl sulfate), Zeaxanthin (from Calendula

LET 16268

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: KIRINE

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/23/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.

Michael P. Devereux Chief Financial Officer